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# EUROPEAN PATENT APPLICATION

21 Application number: 80302328.2

51 Int. Cl.<sup>3</sup>: G 01 N 33/52  
 A 61 B 10/00

22 Date of filing: 09.07.80

30 Priority: 09.07.79 US 55636

43 Date of publication of application:  
 14.01.81 Bulletin 81/2

84 Designated Contracting States:  
 AT BE CH DE FR GB IT LI LU NL SE

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54 Device for obtaining stool samples.

57 A device usable by a patient to self-obtain a stool sample particularly for use in testing for gastro-intestinal bleeding. The device is a multi-layered package (2) the patient can use in privacy, in the same manner as toilet tissue to obtain the stool sample after defecation. Excess stool sample is discarded in the toilet by peeling off one (4) of the layers having an opening (6) therein, leaving an appropriate amount of the stool sample retained on a pad (10) located beneath the opening (6). The remaining portion of the package is then sealed and returned to the physician or testing laboratory hermetically sealed. The seal (20) is broken, the test is performed, and then the package is resealed hermetically and discarded.



FIG-2

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"Device for obtaining stool samples"

The invention relates to a stool sampling device which can be used by a patient, in the same manner as toilet tissue, to obtain a stool sample which can then be tested for signs of gastro-intestinal bleeding.

- 5           One medical procedure frequently used on physicians' patients involves the obtaining of a stool sample which is tested for traces of blood to determine the presence or absence of gastro-intestinal bleeding. This test is a conventional precaution for patients having an established history of gastro-intestinal bleeding and will also  
10 be used on patients who are anemic, and who complain of gastro-intestinal discomfort. This test is also used as a screening test during routine physical examinations.

- The procedure most commonly used to obtain the stool sample is for the physician to don a rubber glove and manually insert a  
15 finger into the rectum of the patient to obtain a stool smear. The stool is then transferred to a piece of absorbent paper and effective amounts of detecting agents such as guaiac, ortho-tolidine, or ortho-dianisidine and hydrogen peroxide are applied to the stool whereupon the presence of blood in the stool will cause a bluish  
20 colouration to appear. No colour change indicates the absence of occult blood in the stool, and therefore, the absence of gastro-intestinal bleeding. This method of obtaining the stool sample is not sanitary and is unpleasant for the patient and for the physician.

- 25           Another method of obtaining the required stool samples involves the use of a kit sold under the brand name Hemoccult by Smith Kline Diagnostics. The kit includes a packet made of paper and formed somewhat similarly to a match book. The packet has a tab-slot interlock which can be opened so that the packet can be  
30 unfolded. Inside of the packet there is disposed a sample-receiving pad which has been treated with guaiac, one of the detecting chemicals referred to above. A sample-obtaining wooden stick is included

with the kit. The kit is designed for use by the patient in privacy as follows. The kit is given to the patient by the physician, or obtained at a pharmacy upon a directive of the physician. The patient takes the kit home, and it is used subsequent to defecation. A scraping of the bowel movement is obtained by the patient from the toilet with the stick and some of the scraped material is transferred to the pad from the stick. The contaminated stick must then be discarded by the patient. The packet flap is then reclosed and the packet and sample are then returned to the physician's office for examination. It will be appreciated that this procedure is to some extent more desirable than the first above-described procedure in that it may be performed in privacy. Nevertheless, it is also an unclean procedure with no provision for guarding against contamination, and the manner of disposition of the specimen on the pad is somewhat distasteful in that the stool-contaminated pad is generally discarded in a waste bin in an unsealed state.

Other prior art stool sampling devices are disclosed in U S Patents Nos 3 718 431; 3 672 351 and 3 996 006.

According to the invention there is provided a stool sampling device for obtaining direct anal stool samples, the device comprising: a first sheet of pliant impermeable material; a pad secured to one side of said first sheet and to receive a stool smear when the device is drawn across a patient's anus after defecation; a second sheet of pliant material disposed on said first sheet, and second sheet overlying said one side of said first sheet and including an opening therethrough aligned with the pad; first releasable adhesive means securing the second sheet to the first sheet whereby the second sheet can be peeled off the first sheet after a stool smear has been deposited on the pad; means for hermetically sealing the pad within the first sheet after a stool smear has been deposited on the pad; an opening in the first sheet, which opening is aligned with the pad when the pad is sealed within the first sheet; a pliant impermeable cover sheet hermetically sealing the opening in the first sheet; and second releasable adhesive means securing the cover sheet to the other side of the first sheet, the second adhesive means enabling the cover sheet to be peeled away

from the first sheet to uncover the opening in the first sheet to expose the pad for the application of detecting reagents to the stool smear thereon and enabling the cover sheet to be resealed to the first sheet after the stool smear has been tested.

5           Such a device can be used to procure stool samples, and which may be used in the same manner as toilet tissue is conventionally used after defecation, in the privacy of the patient's home or a toilet in a physician's clinic or office and can be clean and contamination-free. Thus the device can have a number of constituent  
10 layers, excess amounts of stool being removed by tearing off one of the constituent layers which is biodegradable and discarding that layer in the toilet. The portion of the device remaining is then hermetically sealed and returned to the physician's office and can be contamination and odour-free during transport. To examine the  
15 specimen for blood, the sealed package is opened and a reagent applied to the stool sample. Inspection for colour change is made, and the package is resealed and discarded. In this manner, the test can be performed quickly and the discarded package can be both contamination and odour-free.

20           The invention is diagrammatically illustrated by way of example in the accompanying drawings, in which:-

Figure 1 is an exploded perspective view of a preferred embodiment of a stool sampling device according to the invention;

Figure 2 is a perspective view of the device of Figure 1;

25           Figure 3 is a perspective view of the device of Figures 1 and 2 shown after a layer containing excess stool has been removed and discarded;

Figure 4 is a perspective view of the device of Figures 1 and 3 shown after a hermetic seal has been achieved to render the  
30 device contamination and odour-free; and

Figure 5 is a perspective view of the device showing how access to the stool sample is made for performing the test.

Referring to the drawings, a stool sampling device generally denoted 2, is a multi-layered assemblage which has the general  
35 pliancy and feel of a thickened piece of toilet tissue. An upper layer 4 is a sheet of semi-flexible material such as polyethylene

plastic; paper-plastic laminate, or the like. In one half of the upper layer 4 there is an opening 6 and the half of the sheet 4 which contains the opening 6 has deposited thereon a layer 8 of soft fibrous cellulosic material which is flocked onto the sheet 4 and provides the flocked half thereof with a soft texture similar to tissue paper. Thus, one half of the sheet 4 will have a soft, tissue-like texture, and the other half will have a smooth, shiny texture, like plastic.

Disposed beneath the opening 6, there is a pad 10 somewhat enlarged compared with the opening 6, the pad 10 being of absorbent paper, or the like. An adhesive layer 12 underlies the pad 10 and serves to secure the pad 10 and the flocked half of the overlying sheet 4 to a bottom sheet 14, which is formed from an impermeable material such as a paper-plastic laminate, a foil-plastic laminate, or the like. The bottom sheet 14 is also semi-flexible so as to maintain the overall flexibility and pliability of the entire laminate. The layer 12 may take the form of a double-sided sticky tape, or may be simply a layer of sticky, resealable adhesive coated directly onto the sheet 14. If desired, and as shown in Figure 1, disposed on the half of the bottom sheet 14 not covered by the adhesive layer 12 can be a plurality of adhesive buttons 16 which serve releasably to adhere the non-flocked half of the sheet 4 to the sheet 14. The sheet 14 is provided with an opening 18 on one of its halves, and the opening 18 is closed and sealed by means of a conforming closure member 20 made from the same material as the sheet 14. The closure member 20 includes a pull tab 22 and a border 24 of resealable adhesive which serves to secure the closure member 20 to the sheet 14.

The appearance of the device 2 as dispensed by the physician, pharmacy, or the like, in its ready-to-use condition, is shown in Figure 2.

The device 2 is used to obtain a stool sample in the following manner. Immediately after defecation, the device is used in the same manner as one uses toilet tissue, and the flocked portion 8 of the device is drawn across the anus, whereby a stool smear is obtained on the flocked portion 8 and on the portion of the pad 10 which underlies the opening 6. The sheet 4 is then stripped away

from the remaining portion of the device and discarded into the toilet to be flushed away with the stool. It will be noted that the adhesive buttons 16 will easily allow the half of the sheet 4 which overlies them to be removed from the sheet 14 (as shown partially in chain dotted lines in Figure 2) whereupon the remainder of the sheet 4 and the flocked portion 8 thereon will be peeled off the resealable adhesive layer 12.

After the sheet 4 has been removed from the device 2, the remaining portion of the device appears as shown in Figure 3. It will be noted that the pad 10, upon which stool has been deposited, remains adhered to the adhesive layer 12. The half S of the sheet 14 is then folded over on top of other half S' of the sheet 14 to form a pouch configured as shown in Figure 4. The folded-over half S is pressed against the exposed surface of the adhesive layer 12 so as hermetically to seal the resulting pouch whereby contamination and odour from the encased stool sample is prevented. It will be noted that the folding operation brings the sealed opening 18 into overlying relationship with the pad 10.

The sealed pouch is then delivered to the physician's office, testing laboratory, or the like, wherein the encased stool sample will be tested for occult blood. To expose the stool sample for testing, the closure member 20 is peeled back from the opening 18, as shown in Figure 5. The appropriate reagents are then applied to the stool sample on the pad 10. After the test has been performed, the closure member 20 is resealed over the opening 18 and the used pouch is discarded, in an hermetically sealed condition, for subsequent disposal, as by incineration or the like. It will be noted that, during the testing procedure, the underlying portion of the sheet 14 provides an impermeable barrier which prevents reagents, fecal material, viruses, bacteria, or the like from seeping through the pouch onto a laboratory bench.

It will be readily appreciated that a device according to the invention can provide means for obtaining a stool sample which is simple and natural to use, which can be used by a patient in privacy, and which circumvents the embarrassing aspects of the prior art devices and procedures. The sample, once obtained, can be hermetically

sealed whereby contamination and odour problems are avoided. Still further, the device enables the actual test to be performed without reagent or contamination leakage occurring, and also enables the discarded tested stool sample to be contained in an hermetically

5 sealed pouch

CLAIMS

1. A stool sampling device for obtaining direct anal stool samples, the device comprising: a first sheet of pliant impermeable material; a pad secured to one side of said first sheet and to receive a stool smear when the device is drawn across a patient's anus after defecation; a second sheet of pliant material disposed on said first sheet, said second sheet overlying said one side of said first sheet and including an opening therethrough aligned with the pad; first releasable adhesive means securing the second sheet to the first sheet whereby the second sheet can be peeled off the first sheet after a stool smear has been deposited on the pad; means for hermetically sealing the pad within the first sheet after a stool smear has been deposited on the pad; an opening in the first sheet, which opening is aligned with the pad when the pad is sealed within the first sheet; a pliant impermeable cover sheet hermetically sealing the opening in the first sheet; and second releasable adhesive means securing the cover sheet to the other side of the first sheet, the second adhesive means enabling the cover sheet to be peeled away from the first sheet to uncover the opening in the first sheet to expose the pad for the application of detecting reagents to the stool smear thereon, and enabling the cover sheet to be resealed to the first sheet after the stool smear has been tested.

2. A stool sampling device according to claim 1, wherein the means for hermetically sealing comprises a portion of the first releasable adhesive means.

3. A stool sampling device according to claim 1 or claim 2, wherein a portion of the second sheet is flocked with a layer of absorbent fibrous material in the area thereof surrounding the opening in the second sheet.

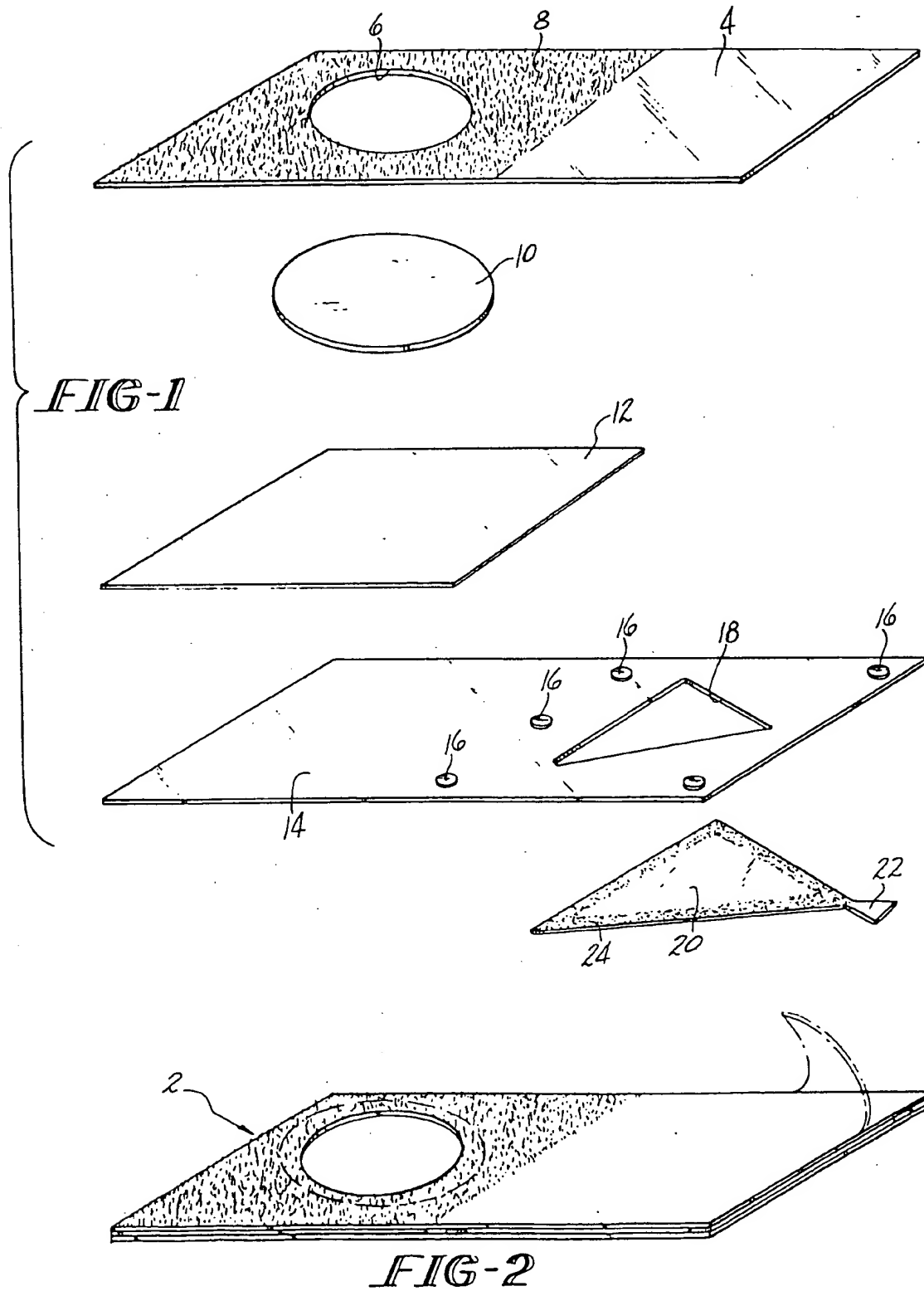
4. A stool sampling device for obtaining direct anal stool

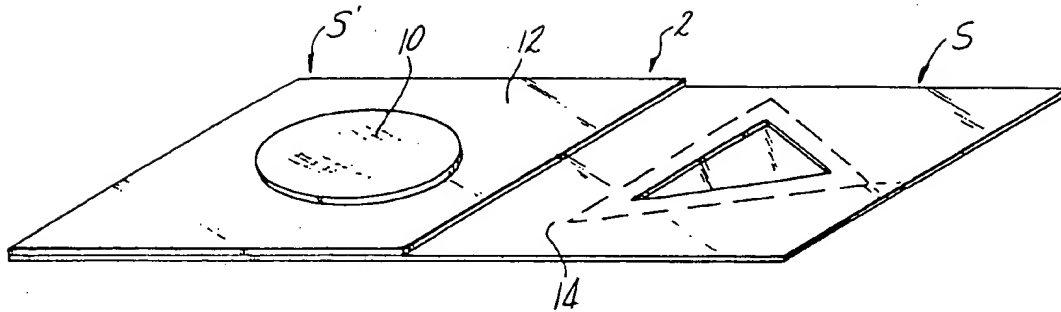
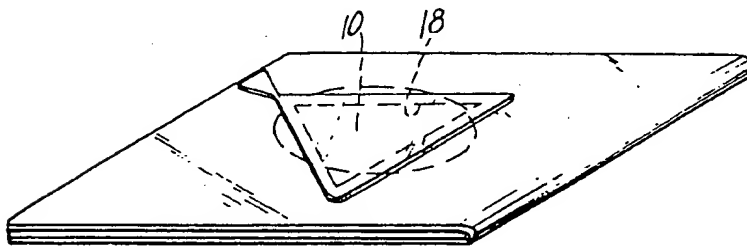
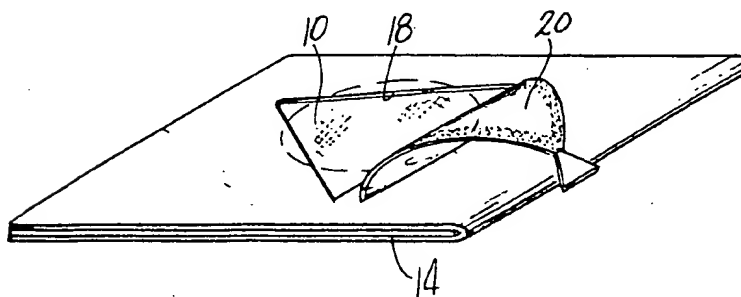


samples, the device comprising: a first elongate sheet of pliant impermeable material having opposed lateral half portions; a pad secured to one side of the first sheet, the pad being situated on one of said half portions of the first sheet to receive a stool smear when the device is drawn across a patient's anus after defecation; a second sheet of pliant material overlying substantially all of said one side of the first sheet, the second sheet including an opening therethrough aligned with the pad, the obverse surface of at least the portion of the second sheet which overlies said one of said half portions of the first sheet being flocked with a layer of absorbent fibrous material; first releasable adhesive means securing the second sheet to the first sheet whereby the second sheet can be peeled off the first sheet after a stool smear has been deposited on the pad, at least a portion of the first adhesive means providing means for hermetically sealing the pad within the first sheet when the other of said half portions of the first sheet is folded over said one of said half portions of the first sheet after removal of the second sheet; an opening in the first sheet through said other half portion of the first sheet, the opening in the first sheet being aligned with the pad when the pad is hermetically sealed within the first sheet; a pliant impermeable cover sheet hermetically sealing the opening in the first sheet; and second releasable adhesive means securing the cover sheet to the other side of the first sheet, the second adhesive means forming means whereby the cover can be peeled away from the first sheet to uncover the opening in the first sheet to expose the pad for the application of detecting reagents to the stool smear, and whereby the cover sheet can be resealed to the first sheet after the stool smear has been tested.

5. A stool sampling device for obtaining direct anal stool samples, the device comprising a pliant sheet-like member; absorbent means on the sheet-like member for receiving a stool smear when the absorbent means is drawn across a patient's anus after defecation; means for forming a hermetically sealed pouch containing the absorbent means after reception of the stool smear on the absorbent

means; and means for opening the pouch for exposing the stool smear for application of chemical reagents thereto.



*FIG-3**FIG-4**FIG-5*



European Patent  
Office

# EUROPEAN SEARCH REPORT

0022377

Application number

EP 80302328.2

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl. 3)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
D	AT - B - 356 825 (BOEHRINGER) + Totality + ---	1,4	G 01 N 33/52 A 61 B 10/00
	US - A - 3 996 006 (PAGANO) + Totality + ---	1,4	
	US - A - 3 965 888 ( BENDER ) + Totality + ----	1,4	
			TECHNICAL FIELDS SEARCHED (Int.Cl. 3)
			A 61 B G 01 N
			CATEGORY OF CITED DOCUMENTS
			X: particularly relevant A: technological background O: non-written disclosure P: intermediate document T: theory or principle underlying the invention E: conflicting application D: document cited in the application L: citation for other reasons
			&: member of the same patent family. corresponding document
X	The present search report has been drawn up for all claims		
Place of search VIENNA		Date of completion of the search 30-09-1980	Examiner SCHNASS

EPO Form 1503-1 08.78